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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: A8461

James E. GALEN

Appln. No.: 09/993,292

Group Art Unit: 1645

Confirmation No.: 5386

Examiner: Duffy, P.

Filed: November 23, 2001

For: USE OF ClyA HEMOLYSIN FOR EXCRETION OF PROTEINS

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of

Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore a check for the fee of \$180.00 under 37 C.F.R. § 1.17(p) is attached.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: January 5, 2005

Substitute for Form 1449 A & B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	09/993,292
			Confirmation Number	5386
			Filing Date	November 23, 2001
			First Named Inventor	James E. GALEN
			Part Unit	1645
			Examiner Name	Duffy, P.
Sheet	1	of	Attorney Docket Number	A8461

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US			
		US			
		US			
		US			
		US			
		US			
		US			
		US			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Su et al. Extracellular export of Shiga toxin B-subunit/haemolysin A (C-terminus) fusion protein expressed in <i>Salmonella typhimurium aroA</i> -mutant and stimulation of B-subunit specific antibody responses in mice. <i>Microbial Pathogenesis</i> 13:465-476 (1992).	
		Saarilahti et al. Fusion of genes encoding <i>Escherichia coli</i> heat-stable enterotoxin and outer membrane protein OmpC. <i>Infection and Immunity</i> 57:3663-3665 (1989).	
		Schodel and Will. Construction of a plasmid for expression of foreign epitopes as fusion proteins with a subunit B of <i>Escherichia coli</i> heat-labile enterotoxin. <i>Infection and Immunity</i> 57:1347-1350 (1989).	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.